FDA'S Laboratory Developed Test Proposed Rule

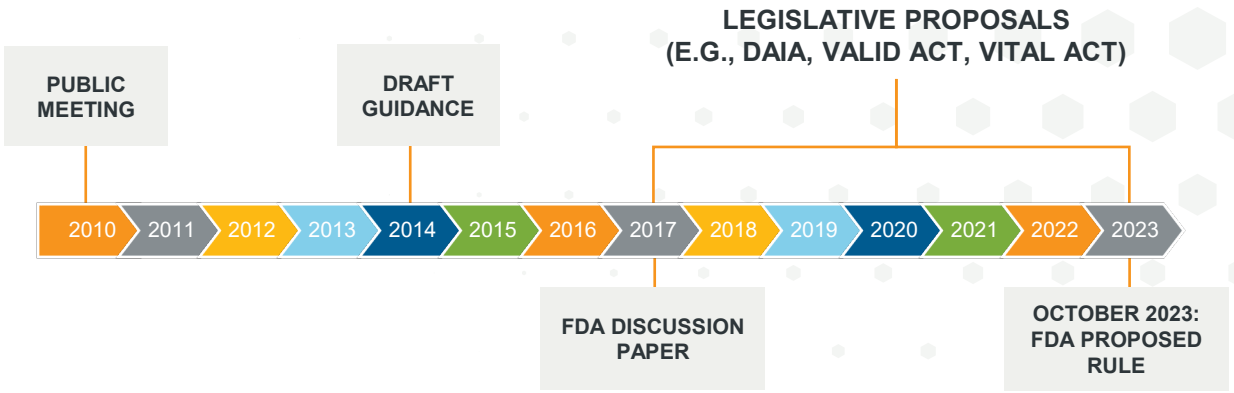
IVDs vs. LDTs

	IN VITRO DIAGNOSTICS (IVDs)	LABORATORY DEVELOPED TESTS (LDTs)
DEFINITION	REAGENTS, INSTRUMENTS, AND SYSTEMS INTENDED FOR USE IN THE DIAGNOSIS OF DISEASE OR OTHER CONDITIONS, INCLUDING A DETERMINATION OF THE STATE OF HEALTH, IN ORDER TO CURE, MITIGATE, TREAT, OR PREVENT DISEASE OR ITS SEQUELAE THAT ARE USED IN THE COLLECTION, PREPARATION, AND EXAMINATION OF SPECIMENS TAKEN FROM THE HUMAN BODY.	TESTS THAT ARE INTENDED FOR CLINICAL USE AND THAT ARE DESIGNED, MANUFACTURED, AND USED WITHIN A HIGH-COMPLEXITY LABORATORY CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA).
REGULATORY STATUS	ACTIVELY REGULATED BY FDA AS "DEVICES" UNDER THE FRAMEWORK FIRST ESTABLISHED UNDER THE MEDICAL DEVICE AMENDMENTS OF 1976 (MDA), WHICH AMENDED THE FEDERAL FOOD, DRUG AND COSMETIC ACT (FDCA) TO CREATE A COMPREHENSIVE SYSTEM FOR THE REGULATION OF DEVICES INTENDED FOR HUMAN USE.	FDA HAS HELD (AND HAS MAINTAINED ITS STANCE OVER THE YEARS) THAT LDTS ARE MEDICAL DEVICES, BUT FOLLOWING ENACTMENT OF THE MDA, GENERALLY PRACTICED DISCRETION OVER ENFORCEMENT OF LDTS.

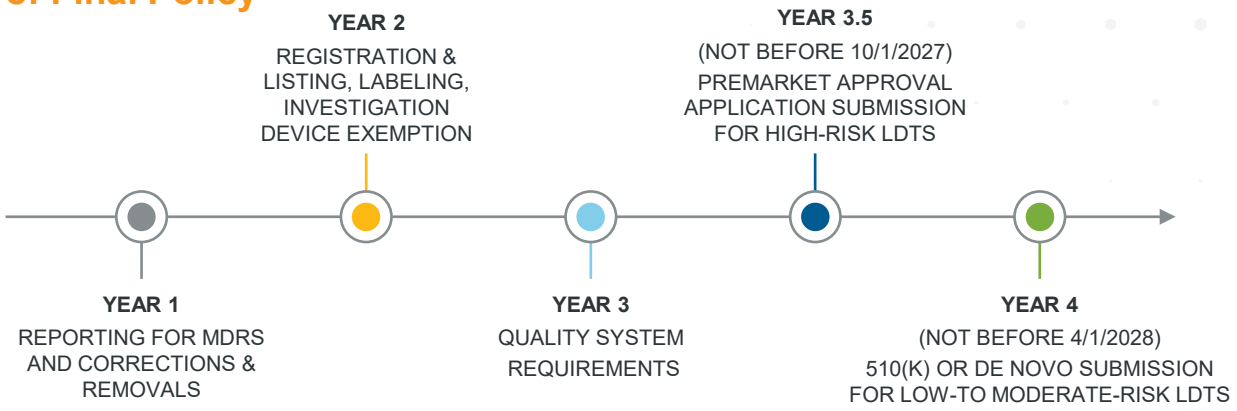
Tests Subject to Phaseout Policy

"IVDS OFFERED AS LDTs"	"IVDS THAT ARE **MANUFACTURED AND OFFERED** AS LDTS" BY HIGH-COMPLEXITY LABORATORIES THAT ARE CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), WHETHER OR NOT THEY FALL WITHIN "FDA'S TRADITIONAL UNDERSTANDING OF AN LDT."
"FDA'S TRADITIONAL UNDERSTANDING OF AN LDT"	FDA HAS GENERALLY CONSIDERED AN LDT TO BE "AN IVD THAT IS INTENDED FOR CLINICAL USE AND THAT IS **DESIGNED, MANUFACTURED, AND USED** WITHIN A SINGLE" HIGH-COMPLEXITY LABORATORY CERTIFIED UNDER CLIA.

Brief History of LDT Oversight Proposals



Proposed Phaseout Policy Timeline Following Publication of Final Policy



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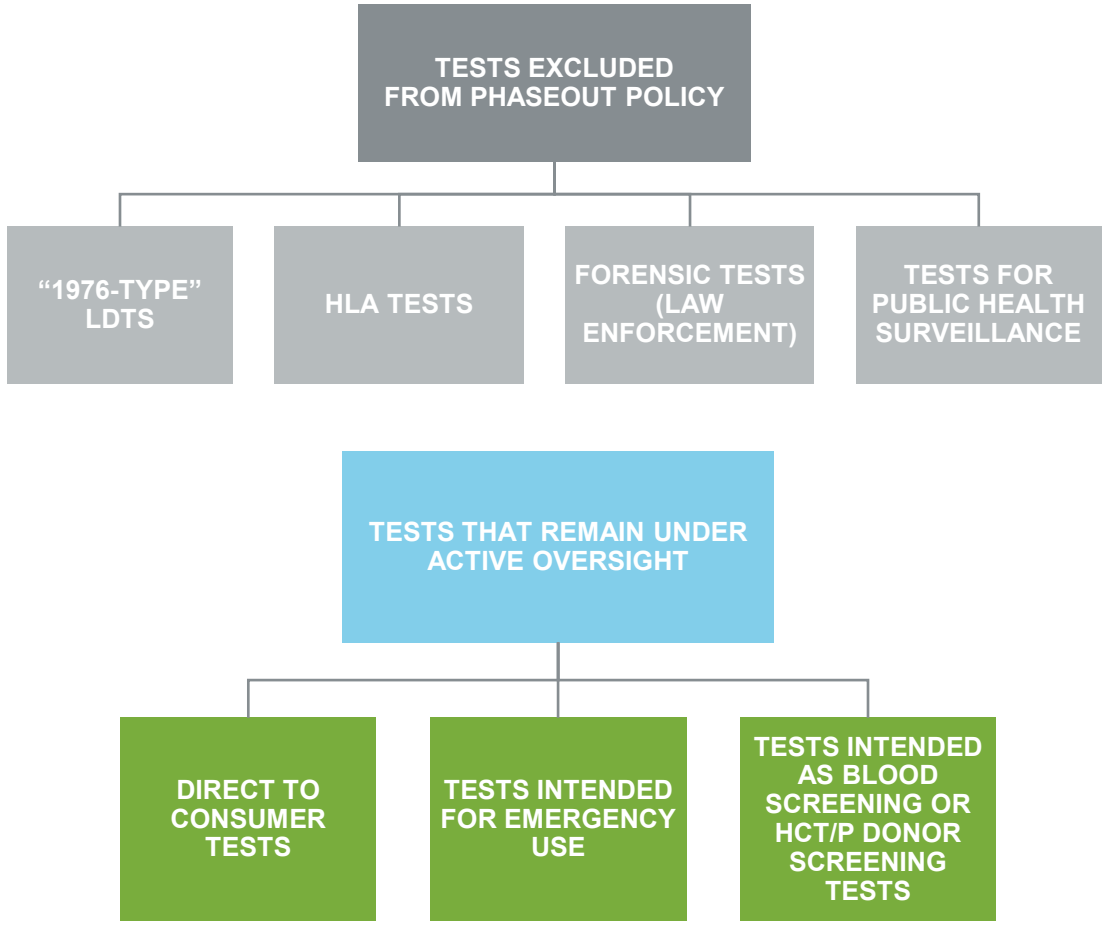
FDA'S Laboratory Developed Test Proposed Rule



User Fees (FY 2024)

PMA APPLICATIONS

APPLICATION TYPE	STANDARD FEE	SMALL BUSINESS FEE*
PMA	$483,560	$120,890**
ANNUAL FEE FOR PERIODIC REPORTING ON A CLASS III DEVICE	$16,925	$4,231

510(K) AND DE NOVO REQUEST

APPLICATION TYPE	STANDARD FEE	SMALL BUSINESS FEE*
510(K)	$21,760	$5,440
DE NOVO CLASSIFICATION REQUEST	$145,068	$36,267

* SMALL BUSINESSES WITH AN APPROVED SMALL BUSINESS DETERMINATION WITH GROSS RECEIPTS OR SALES OF $100 MILLION OR LESS ARE ELIGIBLE FOR A REDUCED FEE.

** SMALL BUSINESSES WITH AN APPROVED SMALL BUSINESS DETERMINATION WITH GROSS RECEIPTS OR SALES OF $30 MILLION OR LESS ARE ELIGIBLE TO HAVE THE FEE WAIVED ON THEIR FIRST PMA.

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Questions Raised by FDA For Comments

GRANDFATHERING

- FOR SOME OR ALL CURRENTLY MARKETED LDTS, SHOULD FDA CONTINUE ITS ENFORCEMENT DISCRETION APPROACH, PARTICULARLY WITH RESPECT TO PREMARKET REVIEW AND SOME OR ALL QUALITY SYSTEM REQUIREMENTS?

SMALL LABORATORIES

- SHOULD FDA ALLOW A LONGER PHASEOUT PERIOD FOR SMALLER LABORATORIES?

ACADEMIC MEDICAL CENTERS (AMCS)

- SHOULD FDA ADOPT DIFFERENT REQUIREMENTS AND GREATER REGULATORY FLEXIBILITY FOR AMCS?

OTHER CIRCUMSTANCES WARRANTING REGULATORY FLEXIBILITY

- IS REGULATORY FLEXIBILITY APPROPRIATE FOR IVDS OFFERED AS LDTS FOR PUBLIC HEALTH SCENARIOS BEYOND WHAT FDA IMPLEMENTED FOR CERTAIN COVID-19 AND MONKEYPOX TESTS?
- WOULD THERE BE UNINTENDED CONSEQUENCES TO CERTAIN PATIENT POPULATIONS (E.G. MEDICARE BENEFICIARIES, RURAL POPULATIONS), AND WHAT STEPS SHOULD BE TAKEN TO MITIGATE THOSE CONSEQUENCES?

LEVERAGING OTHER ACCREDITATION OR VALIDATION PROGRAMS

- SHOULD FDA LEVERAGE PROGRAMS SUCH AS THE NEW YORK STATE DEPARTMENT OF HEALTH CLINICAL LABORATORY EVALUATION PROGRAM OR OTHER PROGRAMS WITHIN THE VETERANS HEALTH ADMINISTRATION?

Key Open Questions

SCOPE OF PHASEOUT POLICY

- WHAT LDTS ARE NOT "MANUFACTURED AND OFFERED" WITHIN THE MEANING OF THE PROPOSED ENFORCEMENT POLICY?
- HOW AND WHEN WILL FDA ENFORCEMENT PRIORITIES SHIFT TO ADDRESS LDTS THAT ARE NOT "MANUFACTURED AND OFFERED" BY A HIGH-COMPLEXITY LABORATORY?

IMPLEMENTATION OF PHASEOUT POLICY

- WILL THE PHASEOUT POLICY ALLOT SUFFICIENT TIME FOR LABORATORY DEVELOPERS TO COME INTO COMPLIANCE WITH THE REQUIREMENTS, PARTICULARLY QS REQUIREMENTS?
- WILL FDA BECOME RESOURCE-CONSTRAINED AND TO WHAT DEGREE AS A RESULT OF THE PHASEOUT POLICY?
- HOW WILL FDA LEVERAGE THIRD PARTIES?

APPLICATION OF REGULATORY REQUIREMENTS TO LDTS

- WILL FDA EXERCISE ADDITIONAL REGULATORY FLEXIBILITY WITH RESPECT TO ANY REGULATORY REQUIREMENTS FOR ALL OR SOME LDTS?
- WHAT GUIDANCE OR ADDITIONAL RESOURCES WILL FDA OFFER OVER THE COURSE OF THE PHASEOUT PERIOD?

HOW WILL THE PHASEOUT POLICY IMPACT OTHER RELEVANT LAWS AND POLICIES?

- PILOTED ONCOLOGY COMPANION DIAGNOSTIC?
- ANALYTE SPECIFIC REAGENTS AND RESEARCH USE ONLY PRODUCTS?
- SUNSHINE ACT?
- COVERAGE AND REIMBURSEMENT PROCESSES (PRIVATE PAYORS OR GOVERNMENT PROGRAMS)?

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